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INSTRUCTION NO. ___

Members of the jury, the instructions I gave at the beginning of the trial and during the trial are still in effect. Now I am going to give you some additional instructions.

You have to follow all of my instructions—the ones I gave you earlier, as well as those I give you now. Do not single out some instructions and ignore others, because they are all important. This is true even though I am not going to repeat some of the instructions I gave you at the beginning of and during] the trial.

[You will have copies of [the instructions I am about to give you now] [all of the instructions] in the jury room.] [You will have copies of some of the instructions with you in the jury room; others you will not have copies of. This does not mean some instructions are more important than others.] Remember, you have to follow all instructions, no matter when I give them, whether or not you have written copies.

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INSTRUCTION NO. ___

I have not intended to suggest what I think your verdicts should be by any of my rulings or comments during the trial.

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You may believe all of what a witness said, or only part of it, or none of it.

You may consider a witness's intelligence; the opportunity the witness had to see or hear the things testified about; a witness's memory, knowledge, education, and experience; any reasons a witness might have for testifying a certain way; how a witness acted while testifying; whether a witness said something different at another time; whether a witness's testimony sounded reasonable; and whether or to what extent a witness's testimony is consistent with other evidence you believe.

In deciding whether to believe a witness, remember that people sometimes hear or see things differently and sometimes forget things. You will have to decide whether a contradiction is an innocent misrecollection, or a lapse of memory, or an intentional falsehood; that may depend on whether it has to do with an important fact or only a small detail.

You will have to decide whether certain facts have been proved by a preponderance of the evidence. A fact has been proved by a preponderance of the evidence if you find that it is more likely than not true. You decide that by considering all of the evidence and deciding what evidence is more believable.

You have probably heard the phrase "proof beyond a reasonable doubt." That is a stricter standard than "a preponderance of the evidence." It applies in criminal cases, but not in this civil case; so put it out of your mind.

Two of the defendants in this case, Midwest Neurosurgeons and DS Medical, are "limited liability companies." I will refer to these as "LLCs."

An LLC acts only through its agents or employees. Any agent or employee of an LLC may bind the LLC by acts or statements made while acting within the scope of the authority delegated to the agent by the LLC, or within the scope of his or her duties as an employee of the LLC.

If you find Ms. Seeger liable because of actions she took on behalf of DS Medical, you must also find DS Medical liable. If you find Dr. Fonn liable because of actions he took on behalf of Midwest Neurosurgeons, you must also find Midwest Neurosurgeons liable.

Certain charts and summaries have been shown to you in order to help explain the facts disclosed by the books, records, or other underlying evidence in the case. Those charts or summaries are used for convenience. They are not themselves evidence or proof of any facts. If they do not correctly reflect the facts shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the books, records or other underlying evidence.

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INSTRUCTION NO. ___

You will remember that certain [schedules] [summaries_] [and charts] were admitted in evidence [as Exhibits ___1 and __]. 870-883. You may use those [schedules] [summaries and] [charts] as evidence, even though the underlying documents and records are not here. [However, the [accuracy] [authenticity] of those [schedules] [summaries] [charts] has been challenged. It is for you to decide how much weight, if any, you will give to them. In making that decision, you should consider all of the testimony you heard about the way they were prepared.]

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INSTRUCTION NO. ___

Although there is more than one defendant in this action, it does not follow from that fact alone that if one defendant is liable, another defendant also is liable. Each defendant is entitled to a fair consideration of the evidence. No defendant is to be prejudiced should you find against another. All instructions I give you govern the case as to each defendant.

The United States' claims involve two separate federal statutes, the False Claims Act and the Anti-Kickback Statute. The United States asserts that Defendants violated the False Claims Act by knowingly presenting, or causing to be presented, claims for Medicare and/or Medicaid reimbursement that were false or fraudulent because the claims implicitly certified that they were in compliance with the Anti-Kickback Statute when they were not. Defendants deny these allegations.

The False Claims Act provides that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval by the government, or who conspires to do so, is liable to the United States.

The Anti-Kickback Statute makes it unlawful to:

- (1) knowingly and willfully solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
 - (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part by Medicare or Medicaid, or
 - (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part by Medicare or Medicaid,

Or

- (2) knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
 - (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part by Medicare or Medicaid, or
 - (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or—ordering any good, facility, service, or item for which payment may be made—in whole or in part by Medicare or Medicaid.

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INSTRUCTION NO. ___

(Verdict Director)

On the United States' claims for violation of the False Claims Act, as to each Defendant individually, your verdict must be for the United States and against the Defendant if you believe, by a preponderance of the evidence, that:

First, the Defendant knowingly presented, or caused to be presented, a claim to the government for payment;

Second, that claim was false or fraudulent because the entity submitting the claim represented that the claim was in compliance with the Anti-Kickback Statute when it was not, as defined in Instruction No. ____; and

Third, the false or fraudulent information was material to the government's decision to pay the claim.

If any of the above elements has not been proved by a preponderance of the evidence, your verdict must be for the Defendant.

[As of March 23, 2010, the Anti-Kickback Statute was amended to [state/clarify] that a claim for Medicare or Medicaid reimbursement that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.]

A "claim" is any request or demand for money where the United States Government provides any portion of the money requested.

A claim is "false or fraudulent" if it is untrue when submitted, made, or used. [Under the law, a claim to Medicare and Medicaid that violates the Anti-Kickback Statute, as defined in Instruction No. __, is a false claim.] A claim is also "false or fraudulent" if the entity submitting it [makes representations in submitting a claim,] [(1) makes a specific representation about the goods or services provided, and (2)] fails to disclose material violations of statutory, regulatory, or contractual requirements, and that failure to disclose makes the representations misleading. [In other words, misleading half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be "false or fraudulent claims."] [The United States need not show that any claim expressly represented that it complied with the Anti-Kickback Statute; it is enough for the United States to show that the claim failed to disclose the Anti-Kickback Statute violation, and that the failure to disclosure this information was material, which I will define for you in a few moments.]

Comment [DKC1]: If the Court accepts the government's proposed language that a claim that violates the AKS is false, we believe that this language in brackets should also be deleted.

"Knowingly" as used in the False Claims Act means that a person, with respect to information, has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information; and requires no proof of specific intent to defraud.

"Actual knowledge" means affirmative knowledge that the claims were false.

"Deliberate ignorance" means that a defendant deliberately closed its eyes to clear warning signs or to what otherwise would have been obvious to it. It also includes situations where a defendant purposely avoided learning all the facts, or suspected a fact but refused to confirm it.

"Reckless disregard" means that a defendant was reckless in determining whether a claim was true or false. An innocent mistake or mere negligence is not sufficient to constitute knowledge under the False Claims Act. But if a defendant failed to make such inquiry as would be reasonable and prudent, that is evidence of "reckless disregard."

"Material" as used above means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. A matter is material if a reasonable person would attach importance to it in determining his or her choice of action; or if the defendant knew or had reason to know that the government attaches importance to the matter.

[When considering whether a violation of the Anti-Kickback Statue is material within the meaning of the False Claims Act, you may consider the fact that, as of March 23, 2010, the Anti-Kickback Statute was amended to [state/clarify] that a claim for Medicare or Medicaid reimbursement that includes items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.] [It is not sufficient for a finding of materiality merely that the Government would have the option to decline to pay if it knew of the Defendant's noncompliance.]

"Caused to be presented" as used above means that the conduct was a substantial factor in producing the harm and that the outcome was foreseeable. You may find that causation was established even if you find that the entity that submitted the claims to the United States did not know that the claims were false. It is not necessary for a defendant to receive the money directly from the government; the defendant's causing the payment of government money to some other individual or entity will suffice.

Comment [DKC2]: We propose the following compromise: We will agree to delete this language if Defendants agree to delete the next sentence, currently in brackets.

In this case, you must find a violation of the Anti-Kickback Statute in order to find the United States has met its burden as to the second element of the False Claims Act. The United States alleges that one way the Anti-Kickback Statute was violated in this case was that Ms. Seeger and DS Medical, LLC knowingly and willfully offered or gave remuneration to Dr. Fonn and Midwest Neurosurgeons, and/or Dr. Fonn and Midwest Neurosurgeons solicited or received remuneration from Ms. Seeger and DS Medical, in order to induce, or in exchange for, arranging for or recommending the purchase or ordering of spinal implants through DS Medical.

The Anti-Kickback Statute is violated if a person:

- (1) Knowingly and willfully solicits or receives remuneration, directly or indirectly; and
- (2) At least one purpose for the solicitation or receipt of the remuneration was in return for arranging for or recommending the purchasing or ordering of an item or service; and
- (3) The item or service may be paid for, in whole or in part, by Medicare or Medicaid.

The Anti-Kickback Statute is also violated if a person:

- (1) Knowingly and willfully offers or pays remuneration, directly or indirectly; and
- (2) At least one purpose of the offer or payment of the remuneration was to induce that person to purchase or order an item or service or to induce that person to arrange for or recommend the purchasing or ordering of an item or service
- (3) The item or service may be paid for, in whole or in part, by Medicare or Medicaid.

In this case, you must find a violation of the Anti-Kickback Statute in order to find the United States has met its burden as to the second element of the False Claims Act. The United States alleges that another way the Anti-Kickback Statute was violated in this case was that Defendants knowingly and willfully solicited and received remuneration from spinal implant companies Amedica and Verticor, in exchange for arranging for or recommending the purchase or ordering of those companies' products by St. Francis Medical Center.

The Anti-Kickback Statute is violated if a person:

- (1) Knowingly and willfully solicits or receives remuneration, directly or indirectly; and
- (2) At least one purpose for the solicitation or receipt of the remuneration was in return for arranging for or recommending the purchasing or ordering of an item or service; and
- (3) The item or service may be paid for, in whole or in part, by Medicare or Medicaid.

As used in Instructions __ and __:

"Knowingly" merely requires proof of knowledge of the facts that constitute the offense. An act is done "Knowingly" if the act was done voluntarily and intentionally, not because of mistake or accident. A defendant need not be aware of the specific law or rule that his or her conduct may be violating.

"Willfully" means that an act is done voluntarily and purposely and with the bad purpose either to disobey or disregard the law. In order to act willfully, a defendant must act unjustifiably and wrongly while knowing that his or her actions are unjustifiable and wrong. A defendant need not be aware of the specific law or rule that his or her conduct may be violating.

"Remuneration" includes [any benefit, or] anything of value, [in any form or manner whatsoever,] provided directly or indirectly, overtly or covertly, in cash or in kind.

At least one purpose of the remuneration must be to induce the ordering, purchasing, arranging or recommending of items or service which may be paid for in whole or in part by Medicare or Medicaid. It is not a defense that there might have been other purposes for the remuneration, if you find by a preponderance of evidence that at least one of the purposes for the remuneration was the ordering, purchasing, arranging, or recommending of items to be paid for by Medicare or Medicaid. It is not enough if the one purpose is too small to have a realistic impact on the conduct of the Defendants.

"To induce" means an attempt to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.

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Under the False Claims Act, defendants are jointly and severally liable. That means that the United States can recover the total sum of damages only once from any or all of the defendants whom you find have violated the False Claims Act. Thus, if you find that the defendants violated the False Claims Act, you should determine the amount of damages for which each individual defendant may be responsible. If you find that more than one defendant is responsible for the same damages, you should not concern yourself with how the damages are apportioned among the defendants; that is the Court's job.

INSTRUCTION NO. ___

With respect to the United States' claims for conspiracy to violate the False Claims Act, as to each Defendant individually, your verdict must be for the United States and against the Defendant if you believe, by a preponderance of the evidence, that:

First, on or before March 31, 2012, two or more people or entities reached an agreement or understanding to submit or cause the submission of claims for payment to the government which [falsely or fraudulently represented compliance withviolated] the Anti-Kickback Statute;

Second, the defendant voluntarily and intentionally joined in the agreement or understanding, either at the time it was first reached or at some later time while it was still in effect;

Third, at the time the defendant joined in the agreement or understanding, the defendant knew the purpose of the agreement; and

Fourth, while the agreement or understanding was in effect, a person or persons who had joined in the agreement or understanding knowingly did one or more acts for the purpose of carrying out or carrying forward the agreement or understanding.

NOTE: Defendants believe this should reference the AKS instructions under the first element. We will continue to work with Plaintiffs on this point.

NOTE 2: We are also trying to evaluate a proper instruction for damages related to the conspiracy, and will work with Plaintiffs on that as well.

INSTRUCTION NO. ___

Element One requires that two or more people or entities reached an agreement or understanding to submit or cause the submission of claims for payment to the government which [falsely or fraudulently represented compliance with violated] the Anti-Kickback Statute.

The agreement or understanding between two or more people to submit or cause the submission of false claims does not need to be a formal agreement or be in writing. A verbal or oral understanding can be sufficient to establish an agreement or understanding.

It does not matter whether the false or fraudulent claims were actually submitted or whether the alleged participants in agreement actually succeeded in accomplishing their unlawful plan.

The agreement or understanding may last a long time or a short time. The members of an agreement or understanding do not all have to join it at the same time. You may find that someone joined the agreement or understanding even if you find that person did not know all of the details of the agreement or understanding.

INSTRUCTION NO. ___

Element Two requires that the defendant voluntarily and intentionally joined the agreement or understanding.

If you have determined that two or more people reached an agreement or understanding to submit or cause the submission of false claims, you must next decide whether a defendant voluntarily and intentionally joined that agreement or understanding, either at the time it was first formed or at some later time while it was still in effect.

Earlier, in deciding whether two or more people reached an agreement or understanding to submit or cause the submission of false claims, you could consider the acts and statements of each person alleged to be part of the agreement or understanding. Now, in deciding whether a defendant joined the agreement or understanding, you may consider only the acts and statements of that defendant.

A person joins an agreement or understanding to submit or cause the submission of false claims by voluntarily and intentionally participating in the plan with the intent to further the plan to submit false claims. It is not necessary for you to find that the defendant knew all the details of the unlawful plan.

To help you decide whether the defendant agreed to submit or cause the submission of false claims in violation of the Anti-kickback Statute, you should consider the elements of that offense, which are set forth in Instruction No. ___.

INSTRUCTION NO. ____

Element Three requires that the defendant knew the purpose of the agreement or understanding at the time the defendant joined the agreement or understanding.

A person knows the purpose of the agreement or understanding if he or she is aware of the agreement and does not participate in it through ignorance, mistake, carelessness, negligence, or accident. It is seldom, if ever, possible to determine directly what was in the defendant's mind. Thus, the defendant's knowledge of the agreement or understanding and its purpose can be proved like anything else, from reasonable conclusions drawn from the evidence.

It is not enough that the defendant and other alleged participants in the agreement or understanding to submit or cause the submission of false claims simply met, discussed matters of common interest, acted in similar ways, or perhaps helped one another. The defendant must have known of the existence and purpose of the agreement or understanding. Without such knowledge, the defendant cannot be guilty of conspiracy, even if his or her acts furthered the conspiracy.

INSTRUCTION NO. __

Element Four requires that one of the persons or entities who joined the agreement or understanding took some act for the purpose of carrying out or carrying forward the agreement or understanding.

The defendant does not have to personally commit an act in furtherance of the agreement or understanding, know about it, or witness it. It makes no difference which of the participants in the agreement did the act. This is because a conspiracy is a kind of "partnership" so that under the law each member is an agent or partner of every other member and each member is bound by or responsible for the acts of every other member done to further their scheme.

INSTRUCTION NO.

If you determined that an agreement or understanding existed and the defendant joined the agreement, then acts and statements knowingly done or made by a member of the agreement or understanding during the existence of the agreement and in furtherance of it, may be considered by you as evidence pertaining to the defendant, even though the acts and statements were done or made in the absence of and without the knowledge of the defendant. This includes acts done or statements made before the defendant joined the agreement or understanding, because a person who knowingly, voluntarily and intentionally joins an existing conspiracy becomes responsible for all of the conduct of the co-conspirators from the beginning of the conspiracy.

INSTRUCTION NO. ___

If liability for conspiracy under the False Claims Act is established, each conspirator is liable for each of the acts taken for the purpose of carrying out or carrying forward the agreement or understanding and for damages arising from the conspiracy even if he or she did not personally commit all of the acts that may take place under the conspiracy.

One of the issues in this case is whether the defendant acted in "good faith." "Good faith" negates willfulness which is an element of each Count. The essence of the good-faith is that one who acts with honest intentions cannot be found to have acted willfully. The phrase "good faith" includes, among other things, an opinion or belief honestly held, even if the opinion is in error or the belief is mistaken.

The United States has the burden of proving by a preponderance of the evidence that the --- Formatted: Left, Indent: First line: 0.5" defendants acted willfully. Evidence that the defendant acted in "good faith" may be considered by you, together with all the other evidence, in determining whether or not the defendant acted willfully.

NOTE: The Government has agreed to a good faith instruction but is still evaluating the specific +--- Formatted: Left, Right: 0" language.

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There has been evidence that Defendants relied [in good faith-] on the advice of counsel. You may consider the advice given by counsel to a defendant in deciding whether the defendant acted knowingly and willfully. The United States bears the burden to prove by a preponderance of the evidence that defendants acted knowingly and willfully.

In considering the evidence relating to advice of counsel, you may consider all the evidence, including whether defendants in good faith:

- (1) sought the advice of an attorney whom the defendant considered competent for the purpose of securing advice on the lawfulness of the defendant's possible future conduct;
- (2) made a full and accurate report to the attorney of all material facts which the defendant knew; and
- (3) acted in accordance with the advice of the attorney [who had been given a full report].

 [The mere fact of consulting an attorney is insufficient to establish good faith reliance on the advice of counsel.]

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The Anti–Kickback Statute does not prohibit a doctor from making referrals to the distributor, provided there is no remuneration in exchange for or in order to induce those referrals.

Neither the False Claims Act nor the Anti-Kickback Statute prohibits companies or individuals from seeking or earning profits, or seeking to maximize profits.

Consider Damages Only If Necessary

If the United States has proven its claim against Defendants by a preponderance of the evidence, you must determine the damages to which the United States is entitled. You should not interpret the fact that I am giving instructions about the United States' damages as an indication in any way that I believe the United States should, or should not, win this case. It is your task first to decide whether Defendants are liable. I am instructing you on damages only so that you will have guidance in the event you decide that <u>one or more</u> Defendants are liable and that the Government is entitled to recover money from <u>one or more</u> Defendants.

If you find that one or more Defendants violated the False Claims Act, you must award the United States such damages as will reasonably compensate it for such injury and damage as you find, from a preponderance of the evidence in the case, the United States has sustained because of the False Claims Act violations.

For a claim that was false because of a violation of the Anti-Kickback Statute, the measure of the United States' damages is the full amount the United States paid out for the claim.

INSTRUCTION NO. ___

The United States must prove its damages by a preponderance of the evidence.

INSTRUCTION NO. ___

The United States is entitled to all damages it can prove with "reasonable certainty." On the one hand, reasonable certainty does not require proof of damages with mathematical precision. Mere difficulty in ascertaining damages is not fatal to the United States. On the other hand, the United States is not entitled to speculative damages.

INSTRUCTION NO. ___

If you find that one or more defendants violated the False Claims Act, you must determine the number of false or fraudulent claims for which each defendant is responsible.

INSTRUCTION NO. ___

There are rules you must follow when you go to the jury room to deliberate and return with your verdict.

First, you will select a foreperson. That person will preside over your discussions and speak for you here in court.

Second, it is your duty, as jurors, to discuss this case with one another in the jury room.

You should try to reach agreement, if you can do this without going against what you believe to be the truth, because all jurors have to agree on the verdict.

Each of you must come to your own decision, but only after you have considered all the evidence, discussed the evidence fully with your fellow jurors, and listened to the views of your fellow jurors.

Do not be afraid to change your mind if the discussion persuades you that you should.

But, do not come to a decision just because other jurors think it is right, or just to reach a verdict.

Remember you are not for or against any party. You are judges—judges of the facts. Your only job is to study the evidence and decide what is true.

Third, if you need to communicate with me during your deliberations, send me a note signed by one or more of you. Give the note to the [marshal] [bailiff] [court security officer] and I will answer you as soon as I can, either in writing or here in court. While you are deliberating, do not tell anyone—including me—how many jurors are voting for any side.

Fourth, your verdict has to be based only on the evidence and on the law that I have given to you in my instructions. Nothing I have said or done was meant to suggest what I think your verdict should be. The verdict is entirely up to you.

Finally, the verdict form is your written decision in this case. The form reads: (read form)]. You will take this form to the jury room, and when you have all agreed on the verdict,

your foreperson will fill in the form, sign and date it, and tell the [marshal] [bailiff] [court security officer] that you are ready to return to the courtroom.